CLAIMS

1. A composition for treating or preventing an inflammatory or hyperproliferative mucocutaneous disorder, comprising a protease inhibitor and a gelling agent.

2. The composition of Claim 1, wherein the protease inhibitor is an alpha 1-antitrypsin.

3. The composition of claim 2, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

4. The composition of any preceding claim, wherein the protease inhibitor is a modified peptide, biologically active fragment, substantially homologous polypeptide, oligopeptide, homodimer, heterodimer, variant, derivative, and/or an analog of alpha 1-antitrypsin.

5. The composition of any preceding claim, further comprising a physiological buffer at a pH from about 6 to about 9.

6. The composition of claim 5, wherein the buffer has a pH of from about 6.5 to about 7.5.

7. The composition of any preceding claim, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, a polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

8. The composition of any preceding claim, further comprising one or more pharmaceutically active agents.

9. The composition of any preceding claim, which is sterile.

10. Use of a protease inhibitor for the manufacture of a gel composition, for use in preventing or treating an inflammatory or hyperproliferative mucocutaneous disorder.

11. The use of claim 10, wherein the inhibitor is as defined in any of claims 2 to 4.

12. The use of claim 10 or claim 11, herein the composition further comprises a component as defined in any of claims 5 to 8.

13. The use of any of claims 10 to 12, wherein the disorder is a dermatological disorder, disorder of the ear, ocular disorder, disorder of the gastrointestinal tract, or disorder of the urinary tract.

14. The use of claim 13, wherein the disorder is a dermatological disorder selected from atopic dermatitis, skin photodamage, extrinsic skin aging, skin irritation, chronic, burn and ulcer wounds, acne, psoriasis, lichen (particularly lichen planus), basal or squamous cell carcinoma (Bowen's disease), Kaposi's sarcoma, keratosis, disorders of keratinization, and keratoderma.

15. The use of claim 13, wherein the disorder is otitis, conjunctivitis, colitis or interstitial cystitis.

16. A method of making a protease inhibitor gel composition, comprising:

(a) mixing a powdered gelling agent with an aqueous solution to form a gel;

(b) adjusting the pH of the gel to a pH of from about 5.5 to about 9.0;

(c) sterilizing the gel; and

(d) combining a protease inhibitor with the gel to form the protease inhibitor gel.

17. The method of claim 16, wherein the aqueous solution is a physiological buffer.

18. The method of claim 16 or claim 17, further comprising adjusting the pH of the protease inhibitor gel from about 5.5 to about 9.0.

19. The method of any of claims 16 to 18, wherein the protease inhibitor is an alpha 1-antitrypsin.

20. The method of any of claims 16 to 19, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

21. The method of any of claims 16 to 20, wherein the sterilizing comprises irradiation.

22. The method of any of claims 16 to 21, further comprising lyophilizing the protease inhibitor gel.

23. A method of preventing or treating an inflammatory or hyperproliferative mucocutaneous disorder comprising administering to a subject in need thereof an effective amount of a composition comprising a protease inhibitor and a gelling agent.

24. The method of claim 23, wherein the protease inhibitor is an alpha-1 antitrypsin.

25. The method of claim 23, wherein the composition further comprises a physiological buffer at a pH from about 6 to about 9.

26. The method of claim 25, wherein the buffer has a pH of from about 6.5 to about 7.5.

27. The method of claim 23, wherein the gelling agent is hydroxyethyl cellulose, hydroxypropyl cellulose, polyacrylic acid, polyoxyethylene-polyoxypropylene block copolymer, or a combination thereof.

28. The method of claim 24, wherein the alpha 1-antitrypsin is a natural, synthetic or recombinant alpha 1-antitrypsin.

29. The method of claim 23, wherein the composition further comprises one or more pharmaceutically active agents.

30. The method of claim 23, wherein the disorder is a dermatological disorder, disorder of the ear, ocular disorder, disorder of gastrointestinal tract, or disorder of the urinary tract.

31. The method of claim 23, wherein the disorder is a dermatological disorder selected from the group consisting of atopic dermatitis; skin photodamage; extrinsic skin aging; skin irritation; chronic, burn and ulcer wounds; acne; psoriasis; lichen (particularly lichen planus); basal or squamous cell carcinoma (Bowen's disease); Kaposi's sarcoma; keratosis, such as actinic or seborrheic keratosis; disorders of keratinization, such as ichthyosis (particularly lamellar ichthyosis) and keratoderma.

32. The method of claim 23, wherein the disorder is otitis, conjunctivitis, colitis or intestinal cystitis.

33. The method of claim 23, wherein the subject is a mammal.